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| 09/221,931 | 12/28/1998 | TAKASHI TSURUO | WAKAB37.001A | 3902 |

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/221,931

Applicant(s)

Tsuruo et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/18/03
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-34 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on 03/18/2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No, 09/221931 is acceptable and a CPA has been established. An action on the CPA follows.

Status of Claims

2. Claims 11, 17-25 are canceled. Claims 26-34 are added. Claims 26-34 are pending.

3. On the onset, it should be noted that the new set of claims is strictly limited to catechin concentration of $15\mu\text{M}$, which is an *in vitro* concentration. Since it does not seem to be possible to determine administration of which dosage yields this same concentration *in vivo*, it is not possible to compare the invention as claimed with the prior art. Consequently, the art rejections are not applied at this point, pending resolution of issues discussed below in the rejections under 35 U.S.C. 112, first and second paragraphs.

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Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: It is not clear whether contacting cells with a solution of telomerase inhibitor is meant to be under *in vitro* or *in vivo* conditions.

5. Claims 30,31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: It is not clear how varying concentration of catechins in the extract(31) or in telomerase inhibitor (claim 30) yields one single final concentration: the claims recite range of concentrations for catechins; however the base claim 26 is limited to a set concentration of 15 μ M.

6. Claims 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to administering "effective amount" of telomerase inhibitor. However, while specification teaches a broad range of concentrations (500-2000mg/day), it is not clear which dosage is an

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"effective amount" to result in precise concentration of $15\mu\text{M}$ in the vicinity of targeted cells, which is the limitation of the base claim 26.

Claim Rejections - 35 USC § 112, first paragraph.

7. Claim 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claim recites several catechins other than epigallocatechin gallate. The only example in the specification demonstrating effect of the concentration of $15\mu\text{M}$ (which is now limitation of the base claim 26) describes epigallocatechin gallate, EGCG. There is no disclosure in the specification of effect of other catechins in said concentration.

8. Claims 26-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of epigallocatechin gallate, EGCG, in concentration of $15\mu\text{M}$, does not reasonably provide enablement for use of other catechins, or use of crude green tea extract. The only example in the specification demonstrating effect of the concentration of $15\mu\text{M}$ (which is now limitation of the base claim 26) describes epigallocatechin gallate, EGCG. There is no examples of the effect of other catechins, nor there is guidance that other catechins should be used

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in the same concentrations to inhibit telomerase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

9. Further, claims 27, 31 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The claims are drawn to use of green tea extract; however, as applicant acknowledges, "although the catechin content of green tea extract is 93%, it is difficult to estimate the concentration of the resultant catechin solution to be contacted with the cells" (see response filed 03/18/2003, page 5, first paragraph). The specification does not provide guidance or working examples on how to achieve the precise concentration of 15 μ M, required by the base claim 26, using green tea concentrate.

10. Claim 32-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. There is no disclosure that epigallocatechin gallate, or any other catechin, inhibits telomerase *in vivo* in concentration of 15 μ M.

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11. Claim 32-34 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The claims are drawn to administering "effective amount" of telomerase inhibitor, which, according to the base claim 26, should yield concentration of $15\mu\text{M}$ in the vicinity of targeted cells. However, while specification teaches a broad range of concentrations (500-2000mg/day), it does not provide guidance on how to achieve, *in vivo*, the precise concentration of $15\mu\text{M}$, which is the limitation of the base claim 26.

Conclusion.

8. No claims are allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

05/15/03

